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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,845	10/15/2003	Michael T. Lotze	UPT-004	9535
22832	7590	08/18/2006	EXAMINER	
KIRKPATRICK & LOCKHART NICHOLSON GRAHAM LLP STATE STREET FINANCIAL CENTER ONE LINCOLN STREET BOSTON, MA 02111-2950			JUEDES, AMY E	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/688,845

Applicant(s)

LOTZE ET AL.

Examiner

Amy E. Juedes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/27/05</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

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#### DETAILED ACTION

1. Applicant's election with traverse of group V, drawn to a composition comprising an antigen presenting cell and a cytokine, claim 27, in the reply filed on 6/14/06 is acknowledged. Furthermore, Applicant has elected CD34 derived dendritic cells as the species of antigen presenting cells and IL-12 as the species of cytokine.

Applicant's traversal is on the grounds that the election of species is improper since the PTO has not made a *prima facie* showing that generic claim 27 is unpatentable. This is not found persuasive since there is no requirement for the PTO to show that a generic claim is unpatentable before requiring an election of species. Claim 27 is drawn to a composition comprising an antigen presenting cell and a cytokine. The instant specification on pg. 4-5 discloses many structurally and functionally different species of antigen presenting cells and cytokines. Therefore, the election of species requirement is not improper.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim 27 reads on the elected invention and is being acted upon.

2. Applicant's information disclosure, filed 5/27/05, is acknowledged. However, the search report (cite no. C227) has been lined through since it has not been identified by author, title, publisher, date of publication, and relevant pages, as is required. See MPEP § 609.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Bhardwaj et al., 1996, as evidenced by Hackstein et al., 2002.

Bhardwaj et al. disclose a culture (i.e. a composition) comprising ex-vivo purified dendritic cells and IL-12 (see pg. 715 and Table 1 in particular). As evidenced by Hackstein et al., dendritic cells arise from CD34+ stem cells, and thus the ex-vivo isolated dendritic cells taught by Bhardwaj et al. are CD34+ derived. It is noted that the term "therapeutic composition" carries little patentable weight in the absence of evidence of a structural difference, since it refers to an intended use of the composition. The culture medium taught by Bhardwaj et al. (RPMI supplemented with gentamicin, human serum and HEPES buffer) is not incompatible with biological activity and therefore meets the limitations of a "therapeutic composition".

Thus, the reference clearly anticipates the invention.

5. Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Kelleher et al., 1998.

Kelleher et al. disclose a culture (i.e. a composition) comprising dendritic cells and IL-12 (see pg. 750 in particular). Kelleher et al. further teach that said dendritic cells are derived from CD34 bone marrow stem cells (see abstract and pg. 750 in particular). It is noted that the term "therapeutic composition" carries little patentable weight in the absence of evidence of a structural difference, since it refers to an intended use of the composition. The culture medium taught by Kelleher et al. (RPMI supplemented with penicillin, streptomycin, glutamine, FCS, and 2 mercaptoethanol) is not incompatible with biological activity and therefore meets the limitations of a "therapeutic composition".

Thus, the reference clearly anticipates the invention.

6. Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,017,527.

The '527 patent teaches a therapeutic composition comprising dendritic cells in conjunction with cytokines (see column 11 in particular). The '527 patent further teaches that

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the cytokine can be IL-12, and the dendritic cells can be CD34+ derived dendritic cells (see column 1 and 11 in particular).

Thus, the reference clearly anticipates the invention.

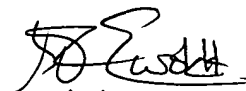
7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.  
Patent Examiner  
Technology Center 1600  
July 26, 2006

  
8/3/06

**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**